

K001160

DEC 11 2000

**510(K) SUMMARY  
OF SAFETY AND EFFECTIVENESS**  
VersaBond™ Bone Cement

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of the VersaBond™ Bone Cement.

Submitted By:	Smith & Nephew, Inc. Orthopaedic Division 1450 Brooks Road Memphis, TN 38116
Date:	July 31, 2000
Contact Person:	Neal Defibaugh Manager - Regulatory / Clinical Affairs
Contact Number	Phone: 901-399-5363
Proprietary Name:	VersaBond™ Bone Cement
Common Name:	Polymethylmethacrylate (PMMA) Bone Cement
Classification Name and Reference:	21 CFR 888.3027 Polymethylmethacrylate (PMMA) bone cement - Class II
Device Product Code and Panel Code:	Orthopedics/87/LOD

**DEVICE INFORMATION**

**A. INTENDED USE**

VersaBond Bone Cement is indicated for use as bone cement in arthroplastic procedures of the hip, knee, and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of osteoarthritis, rheumatoid arthritis, traumatic arthritis, avascular necrosis, nonunion of fractures of the neck of the femur, osteoporosis, secondary severe joint destruction following trauma or other conditions, and revision of previous arthroplasty procedures.

**B. DEVICE DESCRIPTION**

VersaBond™ Bone Cement consists of two separate, premeasured sterilized components which, when mixed, form a radiopaque rapidly setting bone cement.

*One component is supplied in a Tyvek covered PeTG tray. It consists of a 40 g volume (or 60 g volume) powder (copolymer).*

*The other component is supplied in an amber ampoule. It consists of 20 ml liquid (monomer) for 40 g volume; (28.2 ml for 60 g volume).*

The liquid monomer is sterile filtered. The powder is sterilized with ethylene oxide. The Tyvek sealed PETg trays containing the powder as well as the exterior of the ampoule containing the liquid are sterilized with ethylene oxide.

When the powder (copolymer) and the liquid (monomer) are mixed, the dimethyl-p-toluidine (DMpT) in the liquid activates the benzoyl peroxide catalyst in the powder. This initiates the polymerization of the monomer, which then binds together granules of polymer. As polymerization proceeds, a sticky dough-like mass is formed which can be molded. After mixing, the cement can be introduced into the bone cavity and compressed with the use of a pressurizer. The implant should be in place approximately 5-8 minutes (depending on temperature) after mixing the components of the cement, which heats up at approximately 8 minutes and generally hardens by 9 to 15 minutes. Polymerization is an exothermic reaction, which causes heat production. Although the spontaneous generation of heat accelerates the reaction, the polymerization of this self-curing resin occurs even if the temperature is reduced by irrigation with a cool physiologic saline solution.

### C. SUBSTANTIAL EQUIVALENCE INFORMATION

The indications for use, general chemical composition, and design features of the VersaBond™ Bone Cement are substantially equivalent to commercially available bone cements listed below (Table 1— Bone Cement Cleared for Market via PMA)

While the general chemical composition of the VersaBond™ Bone Cement is not identical to all of the commercially available bone cements, any differences that may exist do not significantly affect the safety and effectiveness.

Table 1—Bone Cement Cleared for Market via PMA

Description	Submission Number	Submission Number
Palacos ®R bone cement	Smith & Nephew, Inc., ORT	PMA# P810020
Surgical Simplex ®P RAD	Howmedica Corp.	PMA# N17004



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 11 2000

Mr. Neal Defibaugh  
Manager-Regulatory/Clinical Affairs  
Smith & Newpew, Inc.  
Orthopaedic Division  
1450 Brooks Road  
Memphis, Tennessee 38116

Re: K001160  
Trade Name: VersaBond™ Bone Cement  
Regulatory Class: II  
Product Code: LOD  
Dated: October 9, 2000  
Received: October 10, 2000

Dear Mr. Defibaugh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

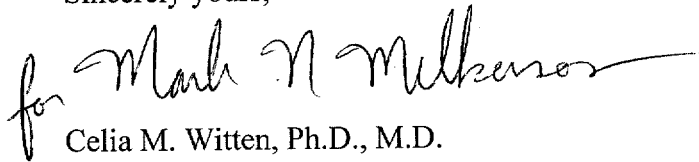
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Page 2 – Mr. Neal Defibaugh

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Mark N. Milken", is written over the typed name.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and

Neurological Devices

Office of Device Evaluation

Center for Devices and

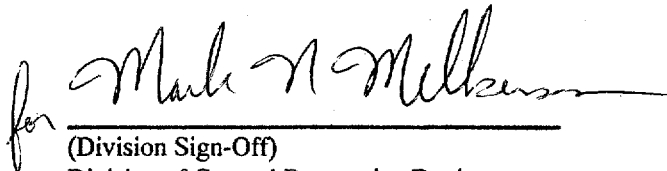
Radiological Health

Enclosure

## INDICATIONS STATEMENT

### VersaBond™ Bone Cement

VersaBond Bone Cement is indicated for use as bone cement in arthroplastic procedures of the hip, knee, and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of osteoarthritis, rheumatoid arthritis, traumatic arthritis, avascular necrosis, nonunion of fractures of the neck of the femur, osteoporosis, secondary severe joint destruction following trauma or other conditions, and revision of previous arthroplasty procedures.

for 

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

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